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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,571	05/23/2001	Thomas Himmler	M0-6341/LEA3	9929

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BAYER CORPORATION
PATENT DEPARTMENT
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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 04/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,571

Applicant(s)

HIMMLER ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

The objection to claims 5 and 9-11 under 37 CFR 1.75 (c), the 112, second paragraph rejection of claims 2, 3, 6, 7 and 8 are rendered moot in light of applicant's amendments at paper no. 6/a.

(new rejections)

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Himmler. (See Reference N) for reasons of record at paper no. 3.

Himmler et. al. teaches the instant compound, 3-Quinolinecarboxylic acid, 8-cyano-1-cyclopropyl-6-fluoro-1,4-dihydro(octahydro-6H-pyrrolo[3,4-b]pyridin-6-yl)-4-oxo-, monohydrochloride, (4aS-cis)--. At page 15, lines 16-20, see Beispiel 2. The difference between the prior art compound and the instantly claimed compounds is the extent of the salt formation. In the instant compound, the salt is semi-hydrochloride of 8-cyano-1-cyclopropyl-7-(1S, 6S-2, 8-diazabicyclo-[4, 3, 0]nonan-8-yl)-6-fluoro-1, 4-dihydro-4-oxo-3-quinolnecarboxylic acid. In the Himmler compound, the salt is a monohydrochloride of 8-cyano-1-cyclopropyl-7-(1S, 6S-2, 8-diazabicyclo-[4, 3, 0]nonan-8-yl)-6-fluoro-1, 4-dihydro-4-oxo-3-quinolnecarboxylic acid. It's axiomatic in organic chemistry that acids

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will react with bases to form salts. Since there are several nitrogen atoms present in the instant compound, it is possible to form 1 to 3 acid-addition salts of HCL. It would have been obvious to one of ordinary skill to form a semihydrochloride from a monohydrochloride of the of 8-cyano-1-cyclopropyl-7-(1S, 6S-2, 8-diazabicyclo-[4, 3, 0]nonan-8-yl)-6-fluoro-1, 4-dihydro-4-oxo-3-quinolnecarboxylic acid. For instance, at page 15, lines 16-20 of the Himmeler reference, see Beispiel 2, where a disclosed species is exemplified. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 1, 9, 10, 11 13, 14, 15, 18, 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

✓ A. Claim 1 recites the limitation "Process for preparing CCDC semihydrochloride according to Claim 1" in line 1 on page 5. There is insufficient antecedent basis for this limitation in the claim.

✓ B. In claims 9, 10, 16-21, the term "medicament", in line 1 is indefinite. Medicament is not a statutory class of invention. The phrase "A pharmaceutical composition" is suggested.

✓ C. In claims 9, 16, 17, 18, the phrase "characterized in that" is indefinite. The term "wherein" is suggested.

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- ✓ D. Claim 13 recites the limitation "Process for preparing CCDC semihydrochloride according to Claim 2" in line 1 on page 8. There is insufficient antecedent basis for this limitation in the claim.
- ✓ E. Claim 14 recites the limitation "Process for preparing CCDC semihydrochloride according to Claim 3" in line 1 on page 9. There is insufficient antecedent basis for this limitation in the claim.
- ✓ F. Claim 15 recites the limitation "Process for preparing CCDC semihydrochloride according to Claim 4" in line 1 on page 26. There is insufficient antecedent basis for this limitation in the claim.
- ✓ G. Claim 13 recites the limitation "Process for preparing CCDC semihydrochloride according to Claim 2" in line 1 on page 8. There is insufficient antecedent basis for this limitation in the claim.
- ✓ H. Claim 19 recites the limitation " A method of preparing a medicament comprising formulating CCDC semihydrochloride according to claim 2" in lines 1-2 on page 12.
There is insufficient antecedent basis for this limitation in the claim.
- ✓ I. Claim 21 recites the limitation " A method of preparing a medicament comprising formulating CCDC semihydrochloride according to claim 1" in lines 1-2 on page 12.
There is insufficient antecedent basis for this limitation in the claim.
- ✓ J. Claim 22 recites the limitation " A process for treating bacteria applying thereto an antibacterial composition containing CCDC semihydrochloride according to claim 2" in lines 1-2 on page 12. There is insufficient antecedent basis for this limitation in the claim.

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K. Claim 23 recites the limitation " A process for treating bacteria applying thereto an antibacterial composition containing CCDC semihydrochloride according to claim 3" in lines 1-2 on page 13. There is insufficient antecedent basis for this limitation in the claim.

L. Claim 24 recites the limitation " A process for treating bacteria applying thereto an antibacterial composition containing CCDC semihydrochloride according to claim 4" in lines 1-2 on page 13. There is insufficient antecedent basis for this limitation in the claim.

M. Claim 11 recites the limitation " A process for treating bacteria applying thereto an antibacterial composition containing CCDC semihydrochloride according to claim 1" in lines 1-2 on page 7. There is insufficient antecedent basis for this limitation in the claim.

N. In claims 4-8, the phrase "at least" is indefinite. There is no upper limit to the number of carbons that be contained in the aliphatic alcohols.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson

April 22, 2002



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